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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,408	05/09/2001	Carlos Schuler	015225-005910US	5388

21968 7590 11/15/2005

NEKTAR THERAPEUTICS  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER
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PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/852,408

Applicant(s)

SCHULER ET AL.

Examiner

Nihir Patel

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on September 12<sup>th</sup>, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1 through 9, 11 through 18 and 24 through 27** are rejected under 35 U.S.C. 102(b) as being anticipated by Bruna et al. (US 5,692,492). **Referring to claim 1**, Bruna discloses an apparatus that comprises a disposable container adapted to contain a drug formulation (**see column 6 lines 1-10**); an aerosol generator for aerosolizing the drug formulation in response to manual actuation (**see column 6 lines 1-10 and column 8 lines 65-67**); an electronic prevention device which prevents manual actuation thereby preventing aerosolization of the drug formulation when in an inactive state and which permits manual actuation thereby permitting aerosolization of the drug formulation when an electric current is supplied to place the prevention device in an activated state (**see column 8 lines 55-67 and column 9 lines 1-34**).

**Referring to claims 2 and 18**, Bruna discloses an apparatus wherein the prevention device comprises an electronic lockout device having a lockout element that is positioned in a dose preventing position when in the inactive state, and is movable to a dosing permitting position when electric current is supplied to place the lockout device in the activated state (**see column 8 lines 55-67 and column 9 lines 1-34**).

**Referring to claim 3**, Bruna discloses an apparatus wherein the lockout device further comprises circuitry for supplying electrical current to move the lockout element to the dose permitting position when the lockout device is in the activated state (**see column 9 lines 1-34**).

**Referring to claim 4**, Bruna discloses an apparatus wherein the lockout device further comprises a controller having an associated memory for storing a dosing condition, and wherein the controller is configured to send a signal to place the lockout device in the activated state only after the dosing condition has been satisfied (**see column 10 lines 10-30**).

**Referring to claim 5**, Bruna discloses an apparatus wherein the container comprises a canister, and wherein the aerosol generator comprises a metering valve and an actuator operably coupled to the canister (**see column 6 lines 29-35**).

**Referring to claim 6**, Bruna discloses an apparatus that further comprises a housing **21**, wherein the canister is reciprocally held within at least a portion of the housing between a home position and a dosing position where the actuator is engaged to open the metering valve and to permit the escape of a metered amount of the drug formulation from the canister (**see column 5 lines 55-60; column 6 lines 1-35**).

**Referring to claim 7**, Bruna discloses an apparatus wherein the lockout element is positioned to prevent engagement of the actuator when in the dose preventing position to thereby prevent opening of the metering device (**see column 9 lines 1-34**).

**Referring to claim 8**, Bruna discloses an apparatus wherein the lockout element has a distal end that is engageable with the canister to prevent substantial displacement of the canister into the housing when the lockout element is in the dose preventing position (**see column 9 lines 34-45**).

**Referring to claim 9**, Bruna discloses an apparatus wherein upon placement of the preventing device into the activated state, the distal end of the lockout element is retracted to permit displacement of the canister into the housing and to permit engagement of the actuator to open the metering valve (see column 9 lines 20-30).

**Referring to claim 11**, Bruna discloses an apparatus that further comprises a high-pressure gas source to assist in aerosolizing the drug formulation when the preventing device is in the activated state (see column 6 lines 1-10).

**Referring to claim 12**, Bruna discloses an apparatus that further comprises a dose counter disposed to count the number of doses of the drug formulation dispensed from the container (see column 10 lines 20-26).

**Referring to claim 13**, Bruna discloses an apparatus wherein the container is reciprocatably disposed within a housing, and wherein the dose counter comprises a dose counting circuit positioned to sense when the container has been reciprocated within the housing (see column 10 lines 10-30).

**Referring to claim 14**, Bruna discloses an apparatus wherein the dose counter further comprises a display for indicating if the container contains an amount of drug formulation (see column 10 lines 10-30).

**Referring to claim 15**, Bruna discloses an apparatus that further comprises a nozzle operably coupled to the canister, and wherein the housing further includes a mouthpiece disposed to receive the drug formulation from the nozzle.

**Referring to claim 16**, Bruna discloses an apparatus wherein the mouthpiece has a first end and a second end, and wherein the nozzle is positionable within an opening adjacent the first

end of the mouthpiece to permit the aerosolized drug formulation to be delivered to a patient upon inhalation through the second end of the mouthpiece.

**Referring to claim 17**, Bruna discloses an apparatus that comprises a container having an amount of drug formulation that is aerosolized in response to manual actuation (**see column 6 lines 1-10 and column 8 lines 65-67**); preventing the manual activation of the aerosolization of the drug formulation with an electronic lockout device by maintaining the lockout device is in the inactive state (**see column 8 lines 55-60**); supplying electrical current to the lockout device to place the lockout device in an active state, thereby permitting manual actuation of the aerosolization of the drug formulation (**see column 8 lines 55-67**).

**Referring to claim 24**, Bruna discloses an apparatus that further comprises stopping the supply of the electric current to the lockout device after the drug formulation has been aerosolized (**see column 10 lines 10-20**).

**Referring to claim 25**, Bruna discloses an apparatus that further comprises supplying electric current to the lockout device to permit another dosing only after a certain dosing condition has been satisfied (**see column 10 lines 10-20**).

**Referring to claim 26**, Bruna discloses an apparatus that further comprises counting the number doses aerosolized from the container (**see column 10 lines 10-30**).

**Referring to claim 27**, Bruna discloses an apparatus that further comprises displaying whether the container contains an amount of drug formulation based on the number of aerosolizations (**see column 10 lines 10-30**).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **34 35 and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruna et al. (US 5,692,492) in view of Von Wielligh (US 6,024,097). **Referring to claims 34 and 35**, Bruna discloses the applicant's invention as claimed with the exception disclosing an amount of a nicotine formulation and aerosolizing it. Von Wielligh discloses an apparatus that does disclose an amount of a nicotine formulation and aerosolizing it. Therefore it would have been obvious to modify Bruna's invention by providing an amount of a nicotine formulation and aerosolizing it in order to assist the user on giving up smoking.

**Referring to claim 36**, Bruna discloses the applicant's invention as claimed with the exception of providing a container that contains a drug formulation that contains nicotine. Von Wielligh discloses an apparatus that does provide a container that contains a drug formulation that contains nicotine. Therefore it would have been obvious to modify Bruna's invention by providing a container that contains a drug formulation that contains nicotine as taught by Von Wielligh in order to assist the user on giving up smoking.

Claims **19, 20, 21 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruna et al. (US 5,692,492) in view of Rubsamen et al. (US 5,694,919). **Referring to claims 19, 20, 21 and 22**, Bruna discloses the applicant's invention as claimed with the exception of disclosing a method step of depressing the anister into the housing to the dosing position to

engage the actuator and to release a metered amount of the drug formulation when the lockout device is in the active state. Rubsamen discloses an apparatus that does disclose a method step of depressing the canister into the housing to the dosing position to engage the actuator and to release a metered amount of the drug formulation when the lockout device is in the active state. Therefore it would have been obvious to modify Bruna's invention by providing a method step of depressing the anister into the housing to the dosing position to engage the actuator and to release a metered amount of the drug formulation when the lockout device is in the active state as taught by Rubsamen in order to deliver the desired amount of medicament.

Claims **28, 29, 30, 31 and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruna et al. (US 5,692,492) in view of Jones, Jr. et al. (US 5,724,986). **Referring to claims 28, 29, 30, 31 and 32**, Bruna discloses the applicant's invention as claimed with the exception of disclosing a valve that is only opened when a force is manually applied to depress the canister into the housing. Jones discloses an apparatus that does disclose a valve that is only opened when a force is manually applied to depress the canister into the housing. Therefore it would have been obvious to modify Bruna's invention by providing a valve that is only opened when a force is manually applied to depress the canister into the housing as taught by Jones in order to deliver the required amount of medicament.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

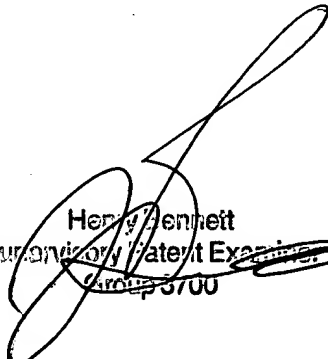


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nihir Patel  
November 8<sup>th</sup>, 2005

  
Henry Bennett  
Supervisory Patent Examiner  
Art Unit 3700